

## **REMARKS**

The present application relates to inbred maize plant and seed PH8CW. Claims 1-10 are pending in the present application. Claim 2 has been amended in the present response. New claims 11 and 12 have been added. Support for new claims 11 and 12 can be found in the specification at page 27, lines 11-19. No new matter has been added by way of amendment. Applicants respectfully request consideration of the claims in view of the following remarks.

### **Detailed Action**

The specification is objected to by the Examiner for the "embedded hyperlink and/or other form of browser-executable code". Applicants have now amended the specification on page 70, to remove the hyperlink and instead just recite the Internet address as in accordance with MPEP § 608.01, thereby alleviating this objection.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 2-3 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. The Examiner states claim 2 is indefinite because "the F1 hybrid maize seed lacks antecedent basis in claim 1". The Examiner also includes dependent claim 3 in the rejection.

Applicants have now amended claim 2 to include proper antecedent basis, thus alleviating this rejection to claims 2-3.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

### **Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1-10 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states the Applicants "describes inbred maize line PH8CW having specific combination of genotypic and phenotypic characteristics that distinguish the line from other corn lines". The Examiner goes on to acknowledge that the

Applicants have described "a single F1 hybrid seed/plant of PH8CW". The Examiner then states "it is unclear if the seed of said F1 hybrid of the inbred PH8CW have been deposited and is publicly available. These are genus claims".

Applicants traverse this rejection. Applicants have satisfied the written description requirement by the actual reduction to practice of F1 hybrid seed/plant produced by inbred maize line PH8CW, by the deposit of a common identifying structural feature of the claimed F1 hybrid seed and plants and by the description of the SSR marker profile in Table 4 of the specification. (See specification, p. 71-74).

The Examiner further states that *Eli Lilly* stands for the proposition that it "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Further, the Examiner cites that "the court stated that to adequately describe a claimed genus, Applicants must describe a representative number of species of the claimed genus, and that one of ordinary skill in the art should be able to 'visualize or recognize the identity of members of the genus'". *Id.* (Office Action, p. 3-4).

Applicants submit that in accordance with the *Eli Lilly* standard recited by the Examiner, the genus of F1 hybrids encompassed by Applicants' claims 1-12 are described with precise definition in a manner which provides structure sufficient to distinguish an F1 hybrid made with PH8CW from an F1 hybrid not made with PH8CW. This is because cells and/or chromosomes of inbred line PH8CW provide an identifying structural feature possessed by all members of the claimed genus. (Specification, p. 71-74). In addition, new claims 11 and 12 were added to further characterize the claimed invention. Therefore, since Applicants have deposited the seed of inbred maize PH8CW and provided the marker profile in Table 4, thereby allowing one skilled in the art to identify the F1 hybrids in relation to the structural feature of the claimed invention, the written description requirement of 35 U.S.C. § 112, first paragraph has been met.

The Examiner states, "Applicant has not described the morphological and/or genotypic characteristics for all hybrid corn plants and seeds produced by crossing the inbred maize line PH8CW with another unidentified maize plant. No specific morphological or genotypic characteristics that distinguish the claimed hybrid corn plants/seeds from other corn plants and seeds are described. The only description recited in the claims is that the hybrid comprises at least one set of chromosomes from inbred PH8CW. This at least one set of chromosomes are

unknown because inbred PH8CW is not genotypically described. In addition, this description is insufficient to provide a distinguishing characteristics, given that all hybrids comprise at least one set of chromosomes from one of its parents". (Office Action, p. 4). The Examiner further states "[t]herefore, the deposit of PH8CW seeds is insufficient to provide an adequate written description of all hybrid progeny that may be produced by crossing PH8CW plants with a second, distinct corn plants". (Office Action, p. 5).

Applicants respectfully traverse this rejection. Most importantly Applicants point out that the SSR profile has been described in the present application and the Examiner's assertion that the "this description is insufficient to provide a distinguishing characteristics" is improper. (Specification, p. 71-74). Further, Applicants may fulfill the written description requirement of § 112, first paragraph by depositing material in a public depository, where the deposited material is not accessible in writing, and where reference to the deposit is made in the specification. *Enzo Biochem, Inc.*, 323 F.3d at 965, 63 U.S.P.Q.2d at 1613. Applicants deposited representative seed of inbred line PH8CW with the ATCC as deposit number PTA-4684. This deposit contributes to the written description the F1 hybrid seed and plants of claims 1-10 and new claims 11 and 12 because it provides the cells and/or chromosomes referenced in the claims. Applicants have further described the SSR marker profile in Table 4 of the specification. It is vital to conceptually understand that all F1 hybrid seed produced with PH8CW will inherit the stable genetics of PH8CW. Thus, Applicants respectfully submit the claimed invention is in accordance with the written description guidelines.

The Examiner states "[g]iven the vast number of hybrids encompassed by the claims" there would be "substantial variation in phenotypes expected among these hybrids" (Office Action, p. 5). Applicants assert that phenotype is not a required element for written description. Rather, the case law requires an identifying characteristic of the genus being claimed. As stated in *University of California v. Eli Lilly*, the identifying characteristic may be structure, formula or chemical composition and does not require phenotype. 43 USPQ2d 1398 (Fed. Cir. 1997).

It is well known to one ordinarily skilled in the art that a hybrid made from an inbred will receive one set of chromosomes from that inbred parent. This is because the genome of a maize inbred line is homozygous. This homozygosity is a consequence of self pollination that occurs during the inbreeding process. As described in the PH8CW specification,

The inbred has been self-pollinated and ear-rowed a sufficient number of generations with careful attention paid to uniformity of plant type to ensure the *homozygosity* and phenotypic stability necessary to use in commercial production. The line has been increased both by hand and in isolated fields with continued observation for uniformity. No variant traits have been observed or are expected in PH8CW. (Specification, p. 21, lines 21-25, emphasis added).

Exhibit 1, submitted herewith, is a visual representation of the fact that most of the cells in a corn inbred will have two essentially duplicate sets of ten chromosomes. (For illustrative purposes, the ten chromosomes are represented by three rectangles in the Exhibits).

When the inbred is used to produce an F1 hybrid, the inbred will produce a haploid cell, such as pollen or an ovule. These haploid cells will receive one of the inbred's sets of chromosomes.

As known to one of ordinary skill in the art and as shown in Exhibits 2 and 3, attached herewith, when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid. Therefore, the genus of F1 hybrid seed and plants encompassed by Applicants' claims 1-10 and new claims 11 and 12 all share the common structural attribute of having a complete or near complete set of the unique chromosomes of PH8CW. Stated in patent terms, it can be said that an F1 hybrid made with PH8CW *comprises* the unique chromosomes of inbred PH8CW. This unique set of chromosomes can be described by molecular markers which can be characterized by molecular marker methods known to those of skill in the art. (Specification, p. 7-8 and 71-74). This unique set of chromosomes is described in the SSR profile in the specification on pages 71-74 (Table 4).

The Examiner states that "the instant specification does not describe the sequences of the primers that were used to produce these SSRs" (Office Action p. 5). Applicants direct the Examiner's attention to page 70 lines 12-15 of the specification where it states that "primers used for the SSRs reported herein are publicly available and may be found in the Maize DB at <http://www.agron.missouri.edu/maps.html> (sponsored by the University of Missouri), in Sharopova et al. (Plant Mol. Biol. 48(5-6):463-481), Lee et al (Plant Mol. Biol. 48(5-6); 453-461), or reported herein".

On page 4 of the Office Action, the Examiner states "[f]urthermore, variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each

hybrid has one non-PH8CW parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-PH8CW inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ".

Applicants traverse this argument. Applicants have complied with the written description standard by a reduction to practice and description of sufficient identifiable characteristics of the claimed F1 hybrid seed and plants produced from maize inbred line PH8CW. However, the Examiner is creating a standard of written description that exceeds that required by law. As explained above, the Applicants have provided "distinguishing characteristics" of the claimed genus such that one of skill in the art could "visualize or recognize the identity of members of the genus". To require Applicants to further describe aspects of the claimed invention that are not the point of patentability of the genus extends the written description requirement beyond the legal standard.

According to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others." The unique set of chromosomes developed by Applicants and genetically fixed in inbred maize line PH8CW is an identifying structural characteristic present in both Applicants' seed deposit of PH8CW, the SSR profile of PH8CW in Table 4 of the specification and the genus of F1 hybrid seed and plants produced with PH8CW.

Applicants would also like to note that the Examiner does not specify how the rejection under 35 U.S.C. § 112, first paragraph, applies to claims 7-10. Applicants assert that claims 7-10 are adequately described according to the written description guidelines by virtue of the inbred plant cell being on deposit. One of ordinary skill in the art would know that the pericarp tissue is genetically identical to the maternal parent. It is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. The pericarp tissue that surrounds the seed is 2n maternal tissue only, the embryo is 2n tissue resulting from the fusion of one maternal and one paternal gamete, and the endosperm is 3n tissue resulting from the fusion of two maternal and one paternal gametes. The seed of maize has been described

as a 'one-seeded fruit', where the ovary wall from the maternal parent is transformed into the tough outer pericarp that surrounds the kernel. Therefore, Applicants point out that intact cells from inbred PH8CW will be a component of the F1 hybrid seed produced with PH8CW as the maternal parent. Further, the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH8CW.

Moreover, Applicants have described how to produce an F1 hybrid from inbred maize line PH8CW. (Specification, p. 6, lines 26-34 and p. 7, lines 1-15). By virtue of the deposit of representative seed of line PH8CW, an individual would be able to grow a maize plant, and its parts, from PH8CW seed. It would be routine to cross this plant with another to produce F1 hybrid seed. A genus of F1 hybrids may now be produced because Applicants have invented PH8CW, and Applicants should be entitled to claims encompassing this genus. A person skilled in the art would thus recognize that Applicants were in possession of F1 hybrid maize plants produced from PH8CW. Accordingly, the claims are adequately described by the specification.

The Examiner concludes by stating "[g]iven this unpredictability in the art; the vast number of hybrids encompassed by the claims; the substantial variation in phenotypes expected among these hybrids; the vast number of unidentified non-PH8CW involved in the breeding, the disclosure of a single hybrid of the inbred PH8CW will not provide adequate written description for all F1 hybrids". (Office Action, p. 5).

Applicants traverse this argument. As stated above, the essential test of written description is whether Applicants have demonstrated possession of a claimed invention such that one skilled in the relevant art would recognize that the Applicants were the inventors of the invention as claimed. Applicants have taught that the main utility of an inbred line is to produce F1 hybrid seed and plants. Applicants have made a deposit of inbred PH8CW that fully enables others to make the claimed genus of F1 hybrid seed and plants. The genus of F1 hybrids encompassed by Applicants' claims complies with the written description requirement as explained *supra*. One skilled in the art would thus recognize that Applicants were in possession of F1 hybrid seed and plants produced from line PH8CW as of the filing date of the application.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

## **Summary**

Applicants submit there has been adequate written description of the claimed F1 hybrid genus. The genus of F1 hybrids encompassed by Applicants' claims are described in relation to the cells and/or chromosomes of inbred line PH8CW, which provide an identifying structural feature possessed by all members of the claimed genus. Specifically, the genus of F1 hybrid seed and plants encompassed by Applicants' claims all share the common structural attribute of having a complete set of the chromosomes of PH8CW, and a description of the set of chromosomes is disclosed in Table 4 of the present application. In addition, the F1 hybrid seed also will comprise an intact cell from inbred maize line PH8CW when PH8CW is the maternal parent. Therefore, one of ordinary skill in the art would thus recognize that Applicants were in possession of the claimed genus of F1 hybrid maize seed and plants produced from PH8CW. Applicants have fully satisfied the legal standards for written description as set forth in case law and the written description guidelines.

Applicants further acknowledge that claims 1-10 are deemed free of the prior art. The Examiner further states the prior art fails to teach or suggest a hybrid maize seed/plant produced from the inbred maize PH8CW, wherein the hybrid comprises at least one set of chromosomes of inbred PH8CW. Applicants thank the Examiner for recognizing that prior art hybrids do not comprise one set of chromosomes of inbred PH8CW.

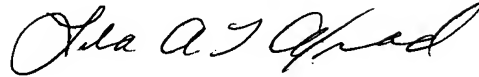
## **Conclusion**

In conclusion, Applicants submit in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Lila A. T. Akrad".

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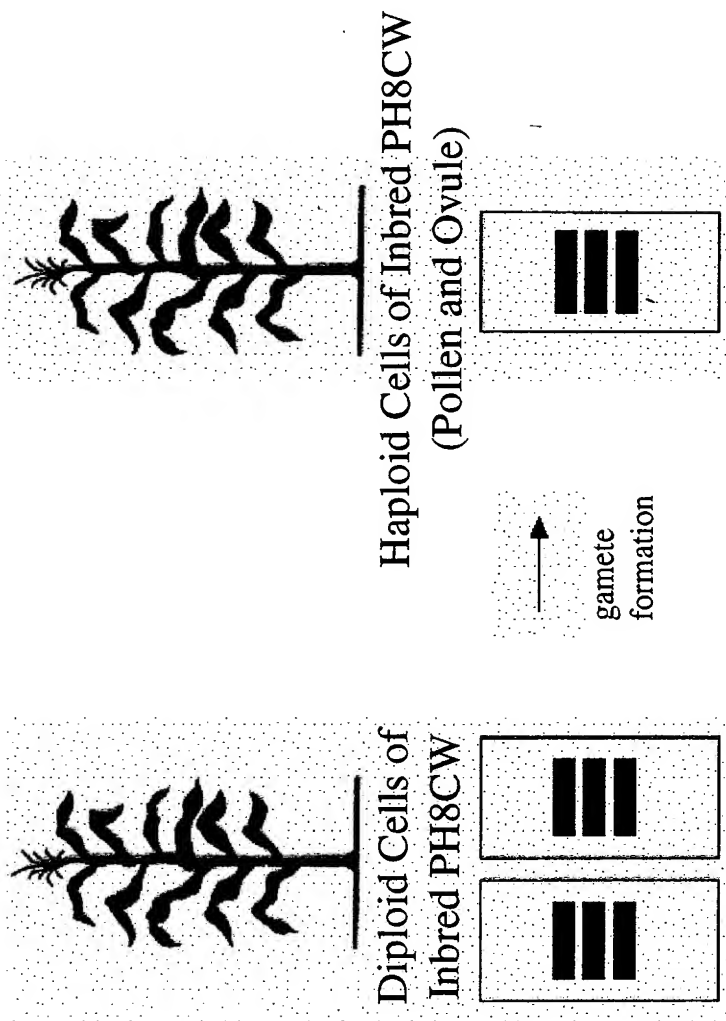
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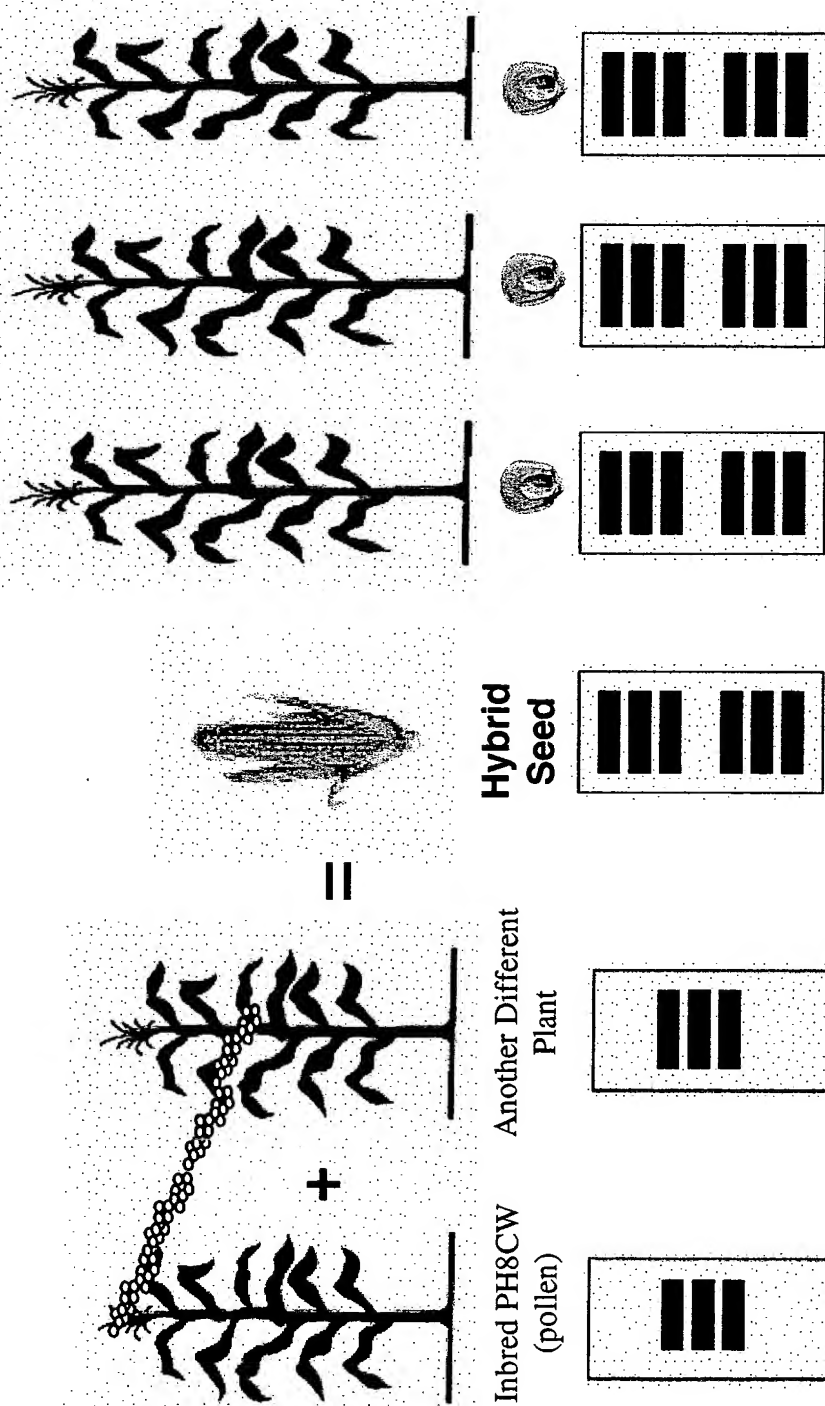
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# Chromosomal View of Inbred PH8CW



# *F1 Hybrid corn seed and plants: PH8CW as Male Parent*



# *F1 Hybrid corn seed and plants: PH8CW as Female Parent*

